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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,670	08/27/2001	Jens Petersen	60117.000007	2509

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EXAMINER

ISABELLA, DAVID J

ART UNIT PAPER NUMBER

3738

DATE MAILED: 09/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/938,670	Applicant(s) PETERSEN ET AL.	
	Examiner DAVID J. ISABELLA	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,7-12 and 44-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,7-12 and 44-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/26/05; 6/20/05</u> | 6) <input type="checkbox"/> Other: _____ |

Status of the Claims

Claims 1,2,5,7-12,44-50 are currently pending. Claims 48-50 are newly presented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,5,7-12,44,45,48-50 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Russian Publication (2127129).

The Russian Publication discloses a hydrogel comprising polyacrylamide cross-linked with methylene bis-acrylamide in a molar ratio between 150:1 to 1000:1 wherein the hydrogel comprises about 0.5 to 3.5% of the polyacrylamide by weight based on the total weight of the hydrogel, and an aqueous solution. While the publication is silent to the ppm of acrylamide/methylene bis-acrylamide monomers and the elasticity module/viscosity of the gel, it appears that since the gel is utilized for the same applications as applicant, these values would be inherent, since the gel is used to emulate and/or match the properties of the tissue being replace/augment.

Claim 2, see page 2 of Publication.

Claims 5,48-50, see page 3 of Publication.

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Claims 7-10,45, see paragraph supra. (ie. the gel is utilized for the same applications as applicant, these values would be inherent, since the gel is used to emulate and/or match the properties of the tissue being replace/augment)

Claim 11, see page 2 of Publication.

Claims 12 and 44, pages 1 and 2 of Publication.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 46,47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russian Publication as applied to claim 1 above, and further in view of Purkait, et al (EP (0727732) and Pavlyk (EP0742022).

While it is not clear if the hydrogel of the Russian Publication is placed within a container prior to replacing/augmenting soft tissue, Purkait teaches the use of similar hydrogel placed within a shell for replacement/augmentation of soft tissues. To use a container/shell to better contain the hydrogel, of the Russian Publication, in vivo to reduce the likelihood of migration of the gel would have been obvious to one with ordinary skill in the art from the teachings of Purkait, et al. Moreover, Pavlyk teaches

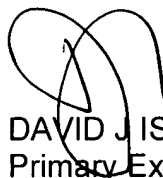
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the combination of the hydrogel and cellular materials to promote engraftment and reducing the likelihood of implant failure or rejections due to fibrous capsule formation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-THURSDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J. ISABELLA
Primary Examiner
Art Unit 3738

DJI
9/26/2005